K100143

510(k) Summary of Safety and Effectiveness

AUG 13 2010

CAO Group, Inc.
4628 West Skyhawk Drive
West Jordan, UT 84084
Tel: 801-256-9282 Fax: 801-256-9287

Robert Larsen,
Preparation Date: July 16, 2010

Device Name:

Trade Name:	Pilot Diode Laser
Common Name:	810nm Diode Laser
Product Classification:	Powered Laser Surgical Instrument

Legally Marketed Predicate Devices for Substantial Equivalence:

Velure Family of Diode Lasers, manufactured by Lasering S.R.L. (K063396)

DenLaser 800 Plus, manufactured by CAO Group, Inc. (K062619)

THOR VR Single Diode Laser Treatment Probe, manufactured by Thor International (K070024)

Rationale for Substantial Equivalence:

The aforementioned laser devices and their accompanying delivery systems share similar indications for use on soft tissue with the submitted device for cutting soft tissue, affecting lesions, photocoagulation, and low level laser therapy for soft tissue relaxation and temporary relief of pain. The predicate devices and submitted device share similar design features including wavelength, operating controls, and laser delivery method. The devices share similar methods of control systems, safety features, and performance monitoring. The devices share similar performance specifications including power output and energy type. The devices share similar applications to soft tissue and indications for use.

Description of Submitted Device:

The Pilot Diode Laser is a device for delivering laser energy to human soft tissue for a variety of surgical procedures and treatments. This energy is generated by solid-state diodes, which provide a consistent and reliable generation of laser energy at 810 ±

20nm for a maximum of 9 watts of energy output. The laser energy is delivered to surgical site by means of a proprietary optical fiber system, which allows for the safe transmission of laser energy to the site without creating undue risk to the patient or operatory staff by errant or collateral laser emissions. The device features some user definable settings, including a switchable 630nm aiming beam, adjustable power output for both the working beam and aiming beam, and continuous delivery or pulse delivery option.

The working end of the delivery fiber is contained within a metal handpiece with a disposable single-use tip. This handpiece system is provided with the device. The activation of the working beam diodes is completed by use of a foot-actuated switch.

Intended Uses of the Pilot Diode Laser system:

The Pilot Diode Laser is indicated for the procedures of

1) Removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue in the medical fields of otolaryngology (ear, nose, and throat), dentistry and oral surgery, arthroscopy, gastroenterology, dermatology, podiatry, general surgery, urology, gynecology, and plastic surgery.

And

2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.

Technological Characteristics and Substantial Equivalence:

The Velure Family of Diode Lasers uses solid state diodes to generate laser energy in the 810nm range. This system uses a fiber delivery system to transmit laser energy to the surgical site. The system also features a 635nm aiming beam and features controls that allow for adjusting the output of the working beam, and switching between a continuous or pulsed-mode laser emission with pulse emissions adjustable from 0.1 – 20 Hz. The maximum output of the working beam is 15 watts.

The DenLaser 800 Plus uses solid state diodes to generate laser energy in the 810nm range. This system uses a fiber delivery system to transmit laser energy to the surgical site. The system also features a 630nm aiming beam and features controls that allow for adjusting the output of the working beam, and switching between a continuous or pulsed-mode laser emission. The device features a wireless foot switch for actuating the working beam. The maximum output of the working beam is 5 watts.

The THOR VR Single Diode Laser Treatment Probe uses solid state diodes to generate laser energy in the 810nm range. This system employs direct emissions from a handpiece containing the laser diode to transmit laser energy to the surgical site. The system features controls that allow for adjusting the pulse rate of the beam from 2.5 – 20,000 Hz. The maximum output of the unit is 0.45 watts.

Conformity to Standards:

The Pilot Diode Laser complies with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated July 26, 2001. The device also complies with the entirety of IEC 60601-1, IEC 60601-1-2, IEC 60601-2-22, IEC 60825-1, UL60601-1, 47 CFR 15 and 18, and ETSI 301-489-1.

Performance Data

The Pilot Diode Laser tested as compliant with 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, dated July 26, 2001 and constructional requirements of IEC 60601-1. This device was tested and found to deliver laser energy necessary for the temporary relief of minor muscle and joint pain, etc. as described in the device's Indications for Use. The device was tested and passed CAO Group internal requirements for construction and performance.

Conclusion

The Pilot Diode Laser is substantially equivalent to the listed laser surgical devices without raising any issues of safety or effectiveness. This device shares similar intended uses, and similar functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CAO Group, Inc.
% Mr. Robert K. Larsen
Regulatory Affairs Manager
4628 West Skyhawk Drive
West Jordan, Utah 84084

AUG 13 2010

Re: K100143
Trade/Device Name: Pilot Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ILY
Dated: August 09, 2010
Received: August 13, 2010

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100143

Indications for Use

AUG 13 2010

510(k) Number (if known): K100143

Device Name: *Pilot Diode Laser*

Indications For Use:

The Pilot Diode Laser is indicated for the procedures of

1) Removal of lesions, excision, incision, vaporization, ablation, hemostasis, and photocoagulation on soft tissue in the medical fields of otolaryngology (ear, nose, and throat), dentistry and oral surgery, arthroscopy, gastroenterology, dermatology, podiatry, general surgery, urology, gynecology, and plastic surgery.

And

2) Temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain, muscle spasm, temporary increase in local blood circulation, and temporary relaxation of muscles by means of topical elevated tissue temperature from infrared spectral emissions.

Prescription Use X **AND/OR** Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100143